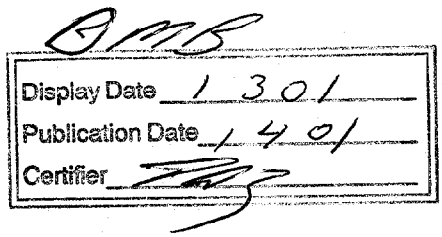
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration



[Docket No. 00N–1678]

Expansion of Medical Device Industry Initiatives

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing some changes in its standard practices for medical device, drug, food, and biologics inspections based on the outcome of the expansion of the medical device industry initiatives pilot program. FDA is discontinuing the practice of post-inspection notification letters for all inspections because the agency now provides inspected establishments with a copy of the establishment inspection report (EIR) when the inspection is deemed closed. FDA has decided to maintain pre-announced inspections and annotations of the inspectional observations (FDA 483) as standard practices for medical device inspections but with respect to inspections of other program areas, to apply these initiatives at the discretion of district management.

DATES: The changes to the medical device and expansion programs are effective January 1, 2001, with the publication of FDA's 2001 edition of the Investigations Operations Manual (IOM). Written comments may be submitted at any time in accordance with FDA's good guidance practices.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise D. Dion, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

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SUPPLEMENTARY INFORMATION: During the FDA/medical device industry grassroots forums in 1995, several issues were discussed concerning FDA's interaction with the medical device industry. A decision was made to consider action on three of the inspectional issues discussed. These included instituting: (1) Pre-announced inspections, (2) listing promised or completed corrective actions on FDA 483 items, and (3) post-inspection notification to establishments regarding their compliance status.

In fiscal year (FY) 1996, FDA initiated a pilot program for the medical device industry, implementing these three changes. The pilot program took place during the 1996 calendar year and was limited to inspections of medical device manufacturers that did not manufacture products that crossed other program areas such as drugs or biologics. Pre-announced inspections were offered to those medical device firms that met the criteria for inclusion in the pilot program. The criteria included nonviolative current good manufacturing practices inspectional histories and a history that records and individuals were available at earlier pre-announced inspections. FDA 483 annotations and the post-inspection notification were done for all medical device inspections whether or not the inspection was pre-announced.

Based on industry input, FDA initiated another year-long pilot program in January 1999, to provide similar coverage for program areas including drugs (both human and animal) and biologics. Food inspections were limited to FDA 483 annotations and post-inspection notification. In FY 2000, FDA considered the impact of the second pilot's effects on field operations. The intent of the medical device pilot program was to optimize resource utilization, enhance FDA/industry communications, and provide firms prompt closure for nonviolative inspections and for corrected inspection observations. However, FDA determined that the additional burdens placed on field staff by the expansion into other program areas failed to capitalize resources and reduced overall field inspectional productivity.

FDA believes that the new inspection method for medical device firms (the quality system inspection technique) implemented in October 1999 provides a clear direction in the inspection

inspection of these establishments, and provides logical stopping points, thus making the time it takes to complete an inspection more predictable. FDA concludes that pre-announcement of medical device inspections will remain standard procedure based on the defined criteria. For other establishments, pre-announcement of inspections remains voluntary at the discretion of the local FDA office. FDA will continue generally not to pre-announce inspections of food, blood bank, and plasmapheresis centers, but this, too, will be left to the district's discretion.

FDA investigators traditionally have discussed their observations with appropriate management at the establishment at the conclusion of the inspection. These discussions are reported in the Establishment Inspection Report. FDA will continue that practice, and will rely on the discretion of the investigator/team to determine whether to annotate the FDA 483. Since the medical device industry specifically asked FDA for annotations of the FDA 483, and since FDA has not found this practice to adversely affect the inspection process for medical devices, annotations will remain standard procedure for medical device inspections only.

In April 1997, FDA implemented a Field Management Directive (FMD 145) that requires FDA field offices to provide a copy of the EIR to the inspected establishment once the inspection is deemed closed. The copy of the EIR is provided along with a letter referred to as the "FMD 145 letter." FDA has found that the issuance of both a post-inspection notification (PIN) letter and a FMD 145 letter is redundant. Because of this redundancy and the burden this puts on the field, the PIN letters will be discontinued in all program areas. FMD 145 will remain in place and these letters will continue to be issued. Establishments will receive a copy of their EIR when the inspection is deemed closed based on 21 CFR 20.64(d).

The 2001 IOM will be posted to FDA's website at www.fda.gov/ora under Inspection References/Investigations Operations Manual. The IOM sections that apply are: 510, 512.3, 516, 529 and 551.1. FMD 145 is posted to FDA's website at www.fda.gov/ora under Inspection References/Field Management Directives.

Dated: 12-27-00
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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

John Marzilli,
Deputy Associate Commissioner for Regulatory Affairs.

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